TISSUE SEPARATOR ASSEMBLY AND METHOD

CROSS REFERENCE TO OTHER APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 60/246,413 filed 7 November 2000 and entitled Tissue Therapy and/or Removal Apparatus and Methods for Use. See also: (1) U.S. Patent No. 6,179,860 issued 30 January 2001 and entitled Target Tissue Localization Device And Method, (2) International Publication No. WO 00/10471 published 2 March 2000 and entitled Target Tissue Localization Device And Method, (3) U.S. Patent No. 6,221,006 issued 24 April 2001 and entitled Entrapping Apparatus And Method For Use, (4) International Publication No. WO 99/39648 published 12 August 1999 and entitled Entrapping Apparatus And Method For Use, (5) U.S. Patent Application No. 09/588,278 filed 5 June 2000 and entitled Tissue Removal Methods And this Apparatus, and (6) International Publication No. WO 00/74561 published 14 December 2000 and entitled Tissue Removal Methods And Apparatus.

BACKGROUND OF THE INVENTION

[0002] The M.D. Anderson Cancer Center in Houston, Texas predicts that cancer will become the leading cause of death in the United States by the year 2002. Cancer presently results in over one thousand five hundred deaths every day in the United States (550,000 deaths every year). Therapy modalities for cancer are plentiful and continued to be researched with vigor. Still, the preferred treatment continues to be physical removal of the cancer. When applicable, surgical removal is preferred (breast, colon, brain, lung, kidney, etc.). Open, excisional, surgical removal is often extremely invasive so that efforts to remove cancerous tissue in less invasive ways continue, but have not yet been perfected.

[0003] The only cure for cancer continues to be the early diagnosis and subsequent early treatment. As cancer therapies continue at earlier stages of diagnosis, the cancerous tissue being operated on is also smaller. Early removal of the smaller cancers demand new techniques for removal and obliteration of these less invasive cancers.

[0004] There are a variety of techniques that attempt to accomplish less invasive cancer therapy, but so far without sufficiently improved results. For example, the ABBI system from U.S. Surgical Corporation and the Site Select system from ImaGyn Corporation, attempt to

accomplish less invasive cancer therapy. However, conventional techniques require more than Minimally Invasive Surgery (MIS) techniques in that they require a large core (that is more than about 15mm diameter) incision. Additionally, the Mammotome system from Johnson and Johnson and MIBB system from U.S. Surgical Corporation also require large core (over about 4mm diameter) access to accomplish biopsy.

[0005] A recent convention held by the American Society of Surgical Oncologists on March 13, 2000 reported that conventional stereotactic core biopsy (SCB) procedures fall short in providing definitive answers to detail precise surgical regimens after this SCB type vacuum assisted biopsy, especially with ductile carcinoma in situ (DCIS). Apparently these percutaneous systems damage "normal" tissue cells so that it is difficult to determine if the cells are "normal damaged" cells or early pre-cancerous (e.g. Atypical Ductal Hyerplasia (ADH)) cells.

[0006] A study presented by Dr. Ollila et al. from the University of North Carolina, Chapel Hill, demonstrated that histology and pathology is compromised using these conventional techniques because of the damage done to the removed tissue specimens. Hence, for many reasons, including the fact that DCIS is becoming more detectable and hence more prevalent in breast cancer diagnosis in the U.S., there is a growing need to improve upon conventional vacuum assisted core biopsy systems.

SUMMARY OF THE INVENTION

[0007] One aspect of the invention is directed to a tissue separator assembly including the proximal end assembly, typically a handle, and catheter assembly extending from the proximal end assembly. The catheter assembly includes a shaft and an elongate tissue separator element, a distal part of which is movable between a retracted state and an outwardly extending, operational state. The proximal end assembly includes a first driver coupled to the tissue separator element and constructed to (1) to move the tissue separator element from the retracted state to the operational state, and (2) automatically rotate the tissue separator element about the axis, whereby a tissue section is separable from the surrounding tissue by the moving tissue separator element.

[0008] Another aspect of the invention is directed to a tissue separator assembly including the proximal end assembly, typically a handle, and catheter assembly extending from the proximal end assembly. The catheter assembly includes a shaft and an elongate tissue separator element, a distal part of which is movable between a retracted state and an outwardly bowed,

operational state. An energy source is selectively coupled to the tissue separator element. The proximal end assembly includes a first driver coupled to the tissue separator element and constructed to (1) to move the tissue separator element from the retracted state to the operational state, and (2) automatically rotate the tissue separator element about the axis, whereby a tissue section is separable from the surrounding tissue by the moving tissue separator element. The catheter assembly also includes a tissue holding element at the distal portion of the shaft movable from a retracted condition to an extended, tissue engaging condition so to help secure a separated tissue section to the catheter assembly. The catheter assembly further includes a tubular braided element at the distal portion of the shaft movable to a radially expanded state so to surround the tissue separator element and any separated tissue section. The proximal end assembly also includes a second driver coupled to the holding element and to the tubular braided element. The second driver is constructed to move the holding element to the extended, tissue engaging condition and move the tubular braided element to the distal, radially expanded state.

[0009] Another aspect of the invention is directed to a tissue separator assembly including the proximal end assembly, typically a handle, and catheter assembly extending from the proximal end assembly. The catheter assembly includes a shaft and a movable tissue separator element. The proximal end assembly includes a first driver coupled to the tissue separator element and constructed to drive the tissue separator element through tissue to separate a tissue section from surrounding tissue. The catheter assembly also includes a tissue holding element at the distal portion of the shaft movable from a retracted condition to an extended, tissue engaging condition so to help secure a separated tissue section to the catheter assembly. The catheter assembly further includes a tubular braided element at the distal portion of the shaft movable to a radially expanded state so to surround the tissue separator element and any separated tissue section. The proximal end assembly also includes a second driver coupled to the holding element and to the tubular braided element. The second driver is constructed to move the holding element to the extended, tissue engaging condition and move the tubular braided element to the distal, radially expanded state.

[0010] A further aspect of the invention is directed to a method for creating a tissue section within surrounding tissue. The method includes positioning a distal end of a catheter assembly at a target location within a patient. An elongate tissue separator element, at the distal end of the catheter assembly, is moved to an outwardly extending, operational state. The separator element is automatically rotated about the axis, following at least the start of the separator element

moving step, so to separate a tissue section from surrounding tissue. The method may also include moving a tissue holding element, located at the distal end of the catheter assembly, from a retracted condition to an extended, tissue engaging condition. Further, the method may include surrounding the separated tissue section with a tubular braided element.

[0011] A still further aspect of the invention is directed to a method for creating a tissue section within surrounding tissue. The method includes positioning a distal end of the catheter assembly at a target location within a breast of a patient. An elongate tissue separator element, at the distal end of the catheter assembly, is moved to a radially extended, outwardly bowed, operational state. Energy is supplied to the separator element. The separator element is automatically rotated about the axis, following at least the start of the separator element moving step, so to separate a tissue section from surrounding tissue. A tissue holding element, located at the distal end of the catheter assembly, is moved from a retracted condition to an extended, tissue engaging condition. The separated tissue section is surrounded by a tubular braided element by moving the tubular braided element, located at the distal end of the catheter assembly, from a proximal, radially contracted state to a distal, radially expanded state following the automatically rotating step.

[0012] Other features and advantages of the invention will appear from the following description in which the preferred embodiments have been set forth in detail in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Figure 1 is a partially schematic overall view of a tissue separator assembly made according to the invention with portions of the handle removed for clarity;

[0014] Figure 1A is a simplified cross-sectional view taken along line 1A -1A of figure 1 showing the engagement of a pin within a slot in the lead nut mounted to the lead screw;

[0015] Figure 2 is schematic view of portions of the drive elements of the assembly of figure 1;

[0016] Figure 3 is a simplified cross-sectional view of the catheter assembly taken along line 3-3 of figure 1;

[0017] Figure 4 is an oblique view of the housing half of figure 1 together with the drive screw, drive nut and an L-shaped actuator connected to and movable with the drive nut;

[0018] Figures 5 and 6 show the handle and catheter assembly of figure 1 after the actuator has moved from the position of figure 1 and the actuator extension has pushed the separator wire pusher screw in a distal direction causing the separator wire to move radially outwardly;

[0019] Figure 7 is a simplified the end view of the block and the pusher screw just after the pusher screw has exited the slot in the block showing the off-vertical orientation of the pusher screw;

[0020] Figure 8 illustrates the proximal end of the lead screw, which is visible from outside the housing, and a rotary position indicator marked thereon corresponding to the position of the separator wire in figure 10;

[0021] Figures 9 and 10 illustrate the structure of figures 5 and 6 after the drive screw has moved the actuator distally causing the lead nut to rotate the lead screw, catheter shaft and separator wire therewith about 540 degrees to create a separated tissue section;

[0022] Figures 11 and 12 illustrate the manual actuation of tissue section holding elements;

[0023] Figure 13 is a simplified view of certain of the components of figure 12;

[0024] Figure 14 is a cross-sectional view of the catheter taken along line 14-14 of figure 13;

[0025] Figures 15 and 16 illustrate the manual actuation of a tubular braided element to surround the separated tissue section; and

[0026] Figure 17 is a simplified view of certain of the components of figure 16.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

[0027] Figures 1 and 2 illustrate a tissue separator assembly 10 used to separate target tissue from surrounding tissue, typically within a patient's breast. The removal of target tissue may be for diagnostic or therapeutic purposes. The assembly 10 includes a catheter assembly 12 extending from a handle 14. Introduction of catheter assembly 12 into the patient, typically through the skin, is preferably aided by the use of, for example, a trocar or an RF tip to provide a suitable path through the tissue. A stepper motor 16 is connected to handle 14 by a drive drive cable 18 and a drive cable connector 20 mounted to the handle housing 22. Note that in the figures only one-half of handle housing 22 is shown; the other housing half is substantially similar. RF energy is supplied to catheter assembly 12 from an RF source 24, along drive cable 18 and to the interior of handle 14. A controller 26 controls the operation of stepper motor 16 as well as RF source 24, such as speed of operation and energy level. Controller 26 also receives

appropriate feedback signals from handle 14 and catheter assembly 12, such as tissue temperature, resistance force signals, rotary orientation, and so forth.

[0028] Drive cable 18 is connected to and rotates a drive screw 28 rotatably mounted within handle 14 at a fixed axial location by drive screw supports 30, 32. A drive nut 34 is threadably mounted to drive screw 28. An L-shaped actuator 36 is secured to drive nut 34. Actuator 36, see figure 4, includes a generally horizontal base portion 38 and a generally vertical upright portion 40 sized and configured to move within handle 14 parallel to the axis of drive screw 28. Therefore, rotation of drive screw 28 by stepper motor 16 causes actuator 36 to slide within housing 22 from the initial position of figure 1 to the position of figure 10. Reverse and reciprocating movement is also possible.

[0029] Catheter assembly 12 includes in introducer sheath 42 mounted to and extending from housing 22. Catheter assembly 12 also includes an actuator tube 43, discussed below with reference to figures 14-17, passing through sheath 42 and a shaft 44 passing through tube 43. See figure 3. Shaft 44 has a distal portion 46 extending distally of the distal end 48 of sheath 42 and a proximal portion 50 extending into the interior of handle 14. Proximal portion 50 is secured to and rotates with a lead screw 52. Accordingly, shaft 44 rotates with lead screw 52. Lead screw 52 is mounted within housing 22 in a manner so that it can rotate but not move axially within housing 22. A tissue separator device 54 extends along shaft 44 and has a separator wire portion 56 secured to the distal end 58 of shaft 44. The separator wire 56 is positioned externally of distal portion 46. The majority of tissue separator device 54 is in the form of a wire and extends through an axial bore 60 formed in shaft 44. The separator device 54 has a radially extending pusher screw 62 at its proximal end. The proximal end of shaft 44 has an axially extending slot 64, see figure 2, through which pusher screw 62 extends. Accordingly, pushing pusher screw 62 distally, that is to the left in the figures, causes tissue separator wire 56 to move outwardly from its radially contracted condition of figure 1 to its radially extended condition of figures 5 and 6. This radially outwardly movement is typically accomplished at the target site within the patient, typically a patient' s breast. To aid movement of separator wire through the tissue, wire 56 is supplied with RF energy from RF source 24. Other applications of energy, such as mechanical reciprocation or mechanical vibration, can also be used.

[0030] The axial movement of pusher screw 62 is caused by the axial movement of actuator 36. Actuator 36 has an extension 66 extending distally from upright portion 40. Extension 66 has a downwardly formed distal end 68 aligned with pusher screw 62. The initial axial

movement of actuator 40, caused by the rotation of drive screw 28 by stepper motor 16, closes a small gap 70 (see figure 2) between distal end 68 and pusher screw 62. This small gap permits the initiation of an electrosurgical arc prior to the outwardly radial movement of separator wire 56. Continued distal movement of actuator 36 moves pusher screw 62 distally causing separator wire 56 to bow outwardly to the position of figures 5 and 6. Figures 5 and 6 (but not figure 1) show the use of a support block 72, which is a part of housing 22, to support the distal end of lead screw 52 and the proximal end of shaft 44. Support block 72 has an axially extending slot 74, see figures 5 and 7, which initially houses pusher screw 62. At the time support wire 56 is fully extended, pusher screw 62 exits slot 74 and the distal end 68 of extension 66, which has a chamfered face, causes pusher screw 62, along with shaft 44, to begin rotating to the off-vertical position of figure 7. At the same time upright portion 40 of actuator 36 closes gap 73 (see figure 2) and contacts a lead nut 75 threadably mounted on lead screw 52. An anti-rotation pin 76 extends from upright portion 40 of actuator 36 and is housed within a U-shaped slot 78 formed in lead nut 74, see figure 1A, to prevent lead nut 74 from rotating around lead screw 52 as lead nut 74 it is moved axially by actuator 36. Instead, the axial movement of actuator 36 causes lead screw 52 to rotate thus rotating shaft 44. Assembly 10 is configured so that shaft 44 rotates about 540 degrees to ensure a tissue section 80 is completely separated from the surrounding tissue by the passage of separator wire 56 through the tissue. The radial position of separator wire 56 can be easily determined by looking at the proximal end 82 of lead screw 52, which is exposed through housing 22. See figure 8. Proximal end 82 has a rotary position indicator 84 formed thereon corresponding to the rotary position of separator wire 56.

[0031] The above described sequence of events, according to this disclosed embodiment, proceeds automatically once initiated by a user. Of course operation of the device, including one or more of extension of separator wire 56, rotation of shaft 44 and energizing wire 56, can be terminated manually or automatically based on, for example, an unexpected resistance to the rotation of shaft 44. With the disclosed embodiment the following events proceed manually; however, the assembly could be designed so that any or all of the following could be accomplished automatically.

[0032] Assembly 10 also includes a T-pusher device 86 having a pair of pusher tabs 88 extending laterally outwardly from slots formed in housing 22. See figures 11-13. After shaft 44 has completed its rotation, the user begins pushing tabs 88 distally. This causes an extension 90 of device 86 to rotate a flipper cam 92 about a pivot pin 94; flipper cam 92 is connected to the

proximal ends of a pair of tissue section holding elements 96. Holding elements 96 are in the form of wires passing through axial bores 98 formed in shaft 44 as shown in figure 3. The distal ends of holding elements 96 are preformed hook wires 100, preferably made of a shape memory material such as nitinol, which pass through openings formed in distal portion 46 of shaft 44 and engage separated tissue section 80 to help secure tissue section 80 to distal portion 46 of shaft 44.

[0033] Device 86 includes a distal end 102 connected to the proximal end of actuator tube 43. Thus, the movement of device 86 causes tube 43 to move distally within introducer sheath 42. At this point, that is with hook wires 100 deployed as an figures 11-13, a tubular braided element 104, see figures 14-17, secured to the distal end of actuator tube 43, is still fully housed within sheath 42. Further distal movement of device 86 causes tubular braided element 104 to extend outwardly past distal end 48 of sheath 42 to the position of figures 15-17. The purpose of tubular braided element 104 is to surround separated tissue section 80 by passing along the dissection plane between the separated tissue section and the surrounding tissue. The open outer end 106 of element 104 naturally expands radially as it is pushed axially through the tissue. To aid the proper initial radial expansion of element 104, shaft 44 has an outwardly tapered guide surface 108, formed on a guide element 110, positioned adjacent to distal end 48 of introducer shaft 42. Guide element 110 has a slot in its proximal surface into which the proximal end of separator wire 56 passes when in the radially expanded condition of figure 9; this helps to keep separator wire 56 from folding over during rotation. If desired, outer end 106 of tubular braided element 104 could include a drawstring or other type of closure element. The separated tissue section 80, now substantially enclosed within tubular braided element 104 and secured to distal portion 46 of shaft 44 by hook wires 100, may be removed from the patient.

[0034] With the present invention separated tissue section 80 retains most if not all of its physical integrity once removed from the patient. Also, the use of tubular braided element 104, especially when it is sealed or otherwise impermeable to the passage of material, helps to reduce the possibility of seeding diseased tissue along the tissue tract during removal of separated tissue section 80.

[0035] Modification and variation can be made to be disclosed embodiments without departing from the subject of the invention as defined in the following claims. For example, a target tissue localization device, such as disclosed in U.S. patent No. 6,179,860, may be incorporated into assembly 10; such a localization device would be deployed, as indicated by dashed lines 112 in figure 1 and localization device actuator shaft 114 in figure 18, after

placement of distal portion 46 of shaft 44 at the target site and would be used to help stabilize the assembly and also help contain, in conjunction with a tubular braided element 104, separated tissue section 80. Lead screw 52 could be hollow to permit actuator shaft 114, or other medical devices, to pass therethrough and into a lumen within shaft 44. Instead of stepper motor 16, drive screw 28 and drive nut 34, other driving mechanisms, such as spring driven drivers with appropriately configured escape mechanisms and/or movement damping devices, could be used. In the preferred embodiment shaft 44 does not begin to rotate until after separator wire 56 has reached its fully radially extended state. In some situations it may be desired to begin rotating shaft 44 before and/or during the outward movement of separator wire 56.

[0036] Any and all patents, patent applications and printed publications referred to above are hereby incorporated by reference.